K962151

RYDER INTERNATIONAL

SEP 18 1996

11. SUMMARY OF SAFETY AND EFFECTIVENESS

Date of Preparation: May 31, 1996

Device Name: Ryder Lacrimal Intubation Set

Common Name: Lacrimal Intubation Set

Classification Name: Lacrimal Probe / Manual Ophthalmic Surgical Instrument per 21 CFR 886.4350

Manufacturer: Ryder International Corporation, 1426 Curt Francis Road, Arab, AL 35016

Contact: Mr. Dan Clark
Ryder International Corporation, 1426 Curt Francis Road
Arab, AL 35016
Telephone: (250) 586-1580
Fax: (205) 586-5553

Predicate: Concept 9035 Guibor Canaliculus Intubation Set

Device Description: The Lacrimal Intubation Set consists of two malleable stainless steel probes (to facilitate insertion) securely attached to a flexible silicone tube of varying thickness. The intubation set is a single-use product, sterilized by gamma radiation.

Intended Use: The Ryder Lacrimal Intubation set is valuable in the reconstruction of the lacrimal outflow system and also useful in canaliculus repair, lacrimal obstruction and complicated and uncomplicated dacryocystorhinostomy procedures.

Technological Characteristics: The design of the predicate device is such that the outside diameter of the silicone tubing is fixed while the Ryder device has variations in the outside diameter of the silicone tubing.

Summary of Safety Testing: Based on the 510(k) "Substantial Equivalence" decision-making process and the information provided herein, we conclude that the new device is substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.